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| 09/554,167 | 07/11/2000 | THIERRY GICQUEL | 72211/9011 | 6758 |

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EXAMINER

PADMANABHAN, KARTIC

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1641

DATE MAILED: 11/05/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/554,167

Applicant(s)

GICQUEL ET AL.

Examiner

Kartic Padmanabhan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-11 and 15-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6-11 and 15 is/are allowed.
- 6) ☒ Claim(s) 16-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 July 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114.

Applicant's submission filed on July 31, 2002 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 16-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 16 recites the limitations "the form" in line 2, "the intensity" in line 5, and "the reaction mixture" in line 6. There is insufficient antecedent basis for these limitations in the claim.

5. Claim 17 recites the limitations "the results" in lines 6-7, "the intensity" in line 9, "the form" in line 10, and "the reaction mixture" in line 14. There is insufficient antecedent basis for these limitations in the claim.

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6. Claim 22 recites the limitations “the intensity” and “the contents” in line 4. There is insufficient antecedent basis for these limitations in the claim. In addition, the limitation of “pressable” is vague and indefinite because it is unclear if the shoe is actually pressed or not.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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10. Claims 16-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uzan et al. (US Pat. 5,849,247) in view of Berthold et al. (US Pat. 5,048,957), Smethers et al. (US Pat. 5,643,535), and Honzawa et al. (US Pat. 5,637,874).

Uzan et al. teaches an automatic immunological assay comprising reaction wells, means for supporting samples to be analyzed, means for supporting reagents, means for taking determined quantities of samples and of reagents and depositing them in reaction wells, means for reading assay results, and means for displacing the wells (col. 1). The reference also teaches means for washing or rinsing the beads in the vessels (col. 2). Furthermore, the reaction modules are formed as single pieces by molding plastics, each comprising eight reaction wells (col. 3). In addition, the reference also teaches the use of a pivoting arm that is used to position reagents or samples (col. 5). A substrate specific to a specific enzyme in the reaction well is deposited in the well, and enzyme interaction takes place, which is followed by reading of the results (col. 7). Uzan et al. also teach horizontal plates for receiving or supporting the washing means and photometric means. The reference does not teach the specific use of vessels with opaque sides, a chemiluminescent substance as the enzyme in the reaction well, a shutter mechanism, or a light proof shoe.

Berthold et al. teach a specimen rack made of radiopaque material, such that each cuvette, except for a region defined by the lower opening cross section of the through chambers and their upper filling opening, is continuously shielded from scattering radiation from adjacent cuvettes (abstract). The reference does not teach the use of a chemiluminescent substance, a shutter, or a light proof shoe.

Smethers et al. teach a luminometer with reduced sample crosstalk comprising an array of sample wells, a photodetector assembly, and means for moving the sample tray and photodetector (abstract). Each well in the array has a structure defining a window through which light can be emitted (col. 2). The reference also teaches the use of luminescence, either chemiluminescence or bioluminescence, as an effective for the determination of a variety of analytes (col. 1). Smethers et al. also teach a photodetector internal-calibration system. This includes a sealed chamber with a light source contained therein, a photosensor, and means for directing the light emitted from the light source to the photodetector when the assembly is positioned at an internal calibration system station. In addition, the reference teaches an external calibration system (col. 2). The reference does not teach the use of a shutter or lightproof shoe.

Honzawa et al. teach a chemiluminescence measuring apparatus comprising a shutter mechanism. The shutter mechanism, when closed, will create a temporary dark chamber that is proof against external light, at which time the photodetector will measure the luminescence. Furthermore, the shutter mechanism includes a rotating hollow chamber, which houses the vessel, a dark box, which can be interpreted as a light-proof shoe, that encompasses the read window, and a photosensing unit, which includes a photomultiplier (col. 2). The rotation of the cylindrical member determines when the shutter opens and closes, and correspondingly when the luminescence is measured. In addition, the dark box portion of the lightproof shoe has an opening that creates an optical path between the vessel and photometric means (col. 2).

It would have been *prima facie* obvious to one of ordinary skill at the time of the invention to use the opaque vessel of Berthold et al. and the chemiluminescent label of Smethers et al. with the vessel of Uzan et al. One would have been motivated to use a chemiluminescent

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label with the vessel of Uzan et al. because they teach the generic use an enzyme specific for a substrate that produces a detectable signal. Chemiluminescent labels are widely used for this purpose, and would have been an obvious choice for use in the vessel. In addition, one would have been motivated to use a vessel or well with opaque sides to reduce the cross talk or contamination of reading between cells. Since opaque sides limit the emission of light to the top-filling opening, other wells will not be contaminated with the results of adjacent wells.

It would have further been *prima facie* obvious to one of ordinary skill at the time of the invention to use the shutter mechanism and light-proof shoe of Honzawa et al. with the modified vessel of Uzan et al. One would have been motivated to use the shutter mechanism to create a temporary dark chamber to obtain a luminescence reading. Furthermore, a shutter mechanism is well known in the art, as the majority of commercially available photometry instruments utilize these mechanisms to take luminescence readings. In addition, a lightproof shoe can be interpreted as any enclosure or part that is impermeable to light. Once again, this is well known in the art, as all photometers utilize this technique. It would have been obvious to use the calibration system of Smethers et al. with the modified device of Uzan et al. in order to ensure accurate readings for the samples. Calibration is also well known in the art, as background readings need to be subtracted to get true luminescence readings.

Allowable Subject Matter

11. Claims 6-11 and 15 are allowed.
12. Claims 6-11 and 15 are allowable over the prior art of record for reasons discussed in the Notice of Allowance mailed on May 3, 2002.

Response to Arguments

13. Applicant's arguments filed July 31, 2002 have been fully considered but they are not persuasive.

14. In response to applicant's argument that the references were impermissibly combined due to the lack of suggestion to combine and the inability of the features of the secondary references to function with the method and apparatus of the primary references, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

15. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

16. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

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17. Applicant's argument that there is no motivation to combine the transparent reaction modules of Uzan et al. with the radiopaque block of Berthold et al. is not persuasive. Since Berthold et al. use a radiopaque block to hold the transparent cuvettes, it would have been obvious that their intention was to protect the reaction cuvettes from external light. Therefore, by simply using opaque cuvettes, one would have been able to achieve the clear intention of Berthold et al. in a more efficient manner, which is ample motivation to undertake this substitution.

18. Applicant's arguments that the Uzan reference does not teach opaque reaction modules is accurate, but the Berthold reference is relied upon to cure this deficiency. In addition, applicant's arguments that neither Smethers or Berthold teach an automated system is similarly not convincing because this feature is taught by the primary reference, Uzan et al.

Conclusion

Claims 6-11 and 15 are allowed, and claims 16-23 are rejected.

References: Ishihara et al. and Carey et al. are cited as art of interest for teaching automated analyzers.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 703-305-0509. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-5207 for regular communications and 703-305-3014 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kartic Padmanabhan
Patent Examiner
Art Unit 1641



October 25, 2002



LONG V. LE
SUPERVISORY PATENT EXAMINER
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11/03/02